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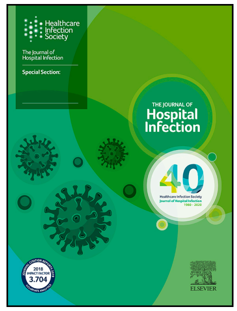

The impact of a healthcare mask mandate on hospital-acquired COVID-19 rates

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PII: S0195-6701(23)00398-5

DOI: https://doi.org/10.1016/j.jhin.2023.12.004

Reference: YJHIN 7107

To appear in: *Journal of Hospital Infection*

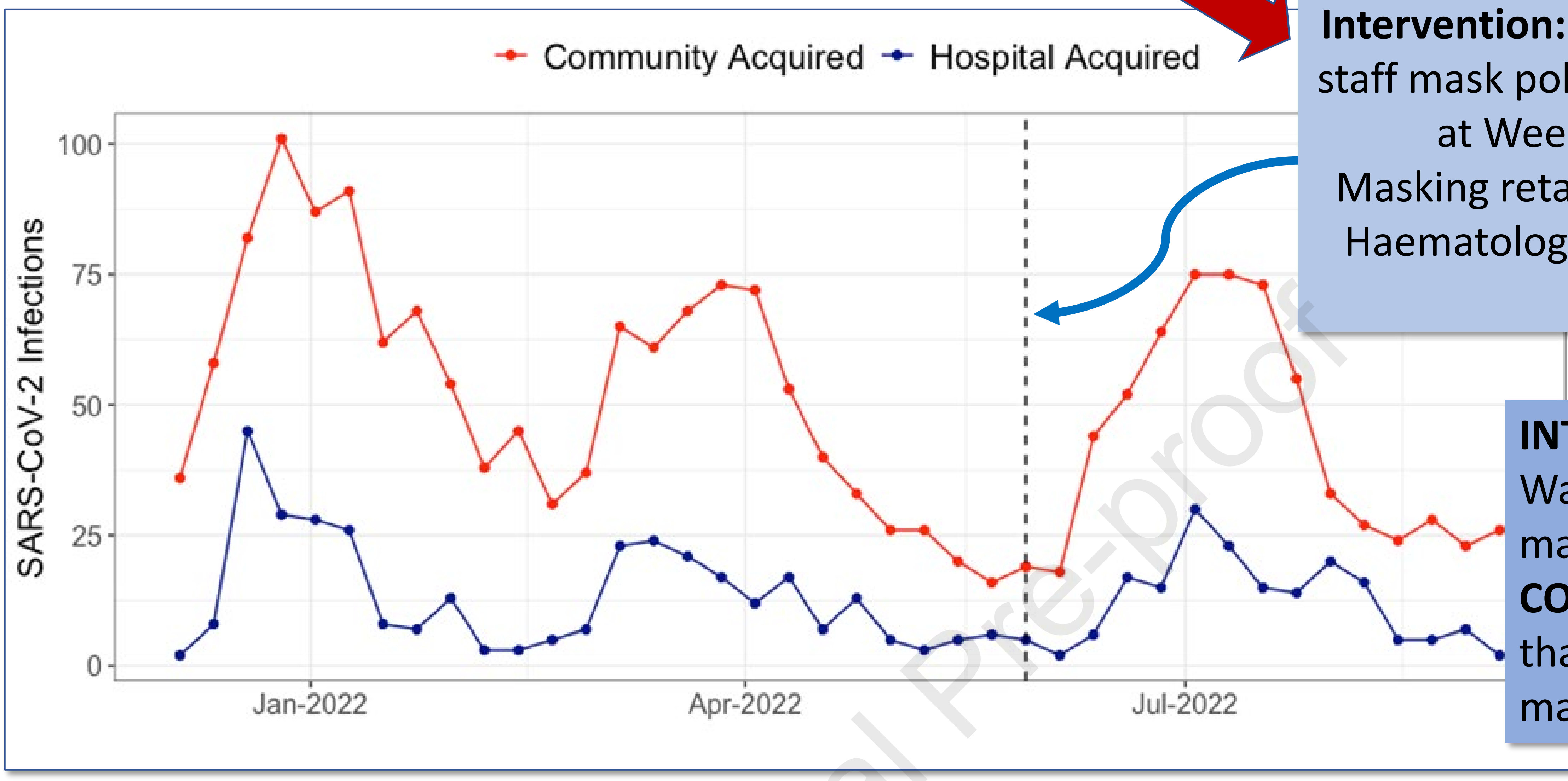
Received Date: 25 October 2023

Revised Date: 28 November 2023

Accepted Date: 6 December 2023

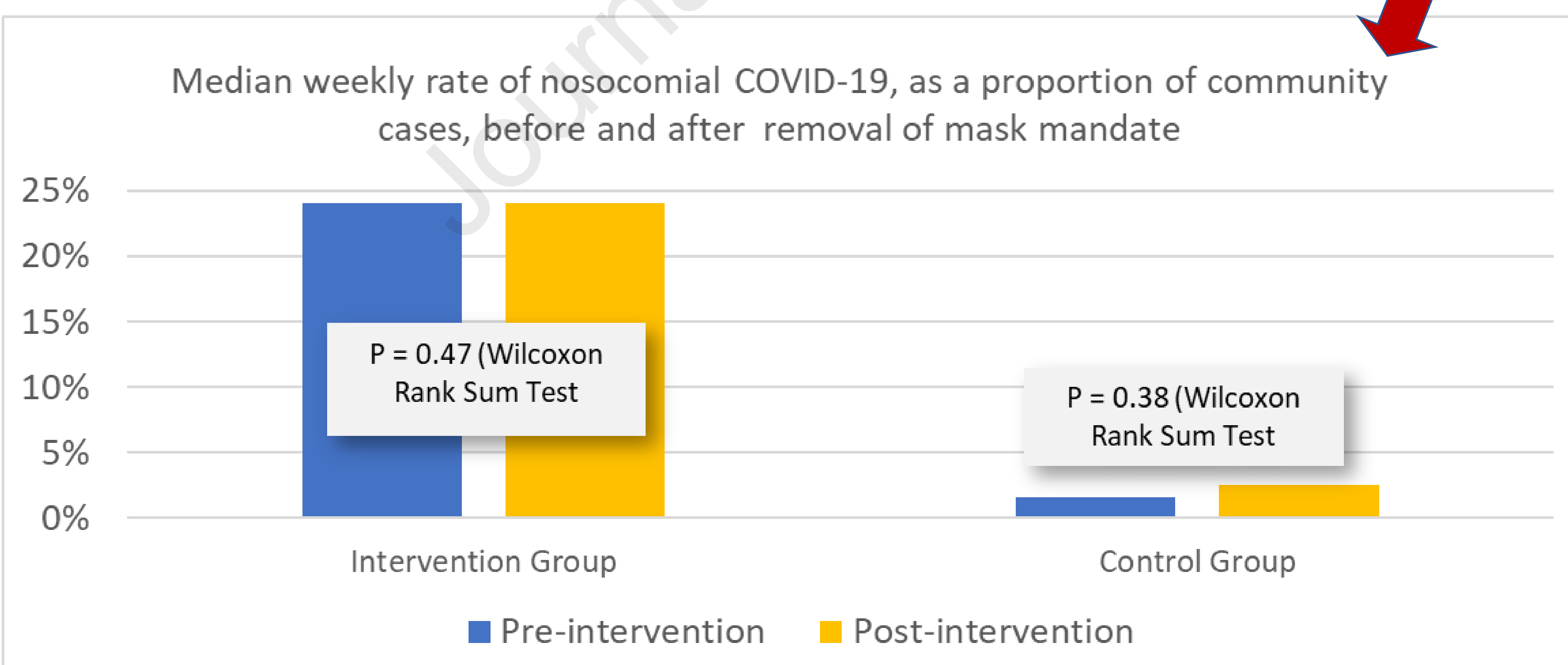
The impact of a healthcare worker mask mandate on hospital-acquired COVID-19 rates

Setting: 1000-bed London hospital:
Surveillance of all COVID-19 cases: December 2021 – Sept 2022 (40 weeks, 2543 cases)



Intervention: Removal of mandatory staff mask policy in designated wards at Week 25 (June 2022); Masking retained in ED/AMU, ITUs, Haematology, Oncology and Renal wards

INTERVENTION GROUP: Wards that removed mask mandate at Week 25
CONTROL GROUP: Wards that retained mask mandate throughout



Further analysis via an **interrupted controlled time-series method**, using a **segmented quasi-poisson regression model**, found no significant trend over the study period, and no significant change in trend post-intervention

Conclusion: Removal of a mask mandate in our hospital was **not** associated with a significant increase in the rate of hospital-acquired COVID-19 cases

The impact of a healthcare mask mandate on hospital-acquired COVID-19 rates

Running title: Healthcare mask mandates and hospital-acquired COVID-19

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Declaration of interest: None

Abstract

Background

Mandatory mask-wearing policies were one of several measures employed to reduce hospital-acquired SARS-CoV-2 infection throughout the pandemic. Many nations have removed healthcare mask mandates, but with the ongoing risk of new SARS-CoV-2 variants or epidemics of other respiratory viruses, it is important to demonstrate the impact of this policy reversal.

Methods

We analysed SARS-CoV-2 infections in a large teaching hospital over 40 weeks in 2022 using a controlled interrupted time series design. The intervention was the removal of a staff/visitor surgical mask-wearing policy for the most wards at week 26 (intervention group) with a subset of specific wards retaining the mask policy (control group). The hospital-acquired SARS-CoV-2 infection rate was adjusted by the underlying community infection rate.

Results

In the context of a surge in SARS-CoV-2 infection, removal of the mask mandate for staff/visitors was not associated with a statistically significant change in the rate of nosocomial SARS-CoV-2 infection in the intervention group (IRR: 1.105, 95% CI: 0.523 to 2.334; p=0.79) and no post-intervention trend (IRR: 1.013 (95% CI: 0.932 to 1.100; p=0.76) to suggest a delayed effect. The control group also found no immediate or delayed change in infection rate.

Conclusion

Using a robust quasi-experimental approach, we found no evidence that removal of a staff/visitor mask-wearing policy had a significant effect on the rate of hospital-acquired SARS-CoV-2 infection. This does not demonstrate that masks were ineffective through the pandemic, but provides some objective evidence to justify the removal of healthcare mask mandates once there was widespread immunity and reduced disease severity.

Keywords:

COVID-19. Healthcare-associated infection. Interrupted time series analysis. Masks. Mask mandate. Pandemic. Policy. SARS-CoV-2.

Introduction

From the beginning of the COVID-19 pandemic, the wearing of face coverings, including face masks, was advocated as an important control measure[1]. Many countries introduced mask mandates, especially in indoor public spaces, on public transport and in hospitals and other healthcare settings[2]. Mask mandates were generally combined with other control measures including social distancing, increased ventilation, limited size of gatherings, and quarantine of COVID-19 cases and contacts.

In the UK National Health Service (NHS), a mask mandate was introduced in June 2020, specifying the use of type IIR, fluid-resistant surgical face masks by all staff and visitors[3]. This had multiple justifications: early evidence that masks reduced SARS-CoV-2 transmission rates, the high rates and severe outcomes from hospital-acquired infection of patients and healthcare workers, the risk of staff shortages even if illness was mild, and a recognition that asymptomatic infection was common[4,5,6]Masking was generally judged to be a reasonable and non-burdensome precaution when faced with a new poorly understood but severe illness with limited treatment options. However, despite wide application of masking and other control measures in healthcare, hospital-acquired infection was common[7], and locally we saw that each community wave of infection was associated with an increase in nosocomial infections (Fig 1).

In December 2020 the first COVID-19 vaccines were administered in the UK, and by the end of 2021 90.1% of the UK population (>12 years old) had been vaccinated with at least one dose[8]. Since December 2021 the Omicron variant has been dominant in the UK: this appears to be more infectious than earlier variants but associated with a lower severity and mortality[9]. In early 2022, in response to widespread vaccination and immunity, and declining severity of COVID-19 as a result, most of the COVID-19 regulations relating to public settings were removed in the UK. The NHS mask mandate remained in place in clinical areas until June 2022, after which decisions about mask policy were devolved to individual hospitals[10].

At the beginning of June 2022, our hospital removed the requirement for staff and visitors to wear masks in most clinical areas, except designated high-risk wards. All patients continued to be screened for SARS-CoV-2 infection on admission by PCR until mid-September 2022, when asymptomatic screening of newly admitted patients stopped, in line with further national policy changes. This gave us an opportunity to explore the rate of hospital-acquired SARS-CoV-2 infection before and after the change in mask policy, to see if we could demonstrate a significant effect. The aim of this study was to use an interrupted time series analysis to assess the impact of the removal of the mask mandate on the rate of hospital-acquired SARS-CoV-2 infection.

Methods

Setting

A university teaching hospital in south-west London with approximately 1000 beds and 10,000 staff.

Data Sources and Intervention

The infection prevention and control team carried out routine surveillance of community-acquired and hospital-acquired SARS-CoV-2 infection of patients admitted to the hospital. We used an anonymised extract of these data for analysis, covering each week between 4th December 2021 (1st week, when the Omicron variant became dominant) and 10th September 2022 (40th week, when universal screening on admission stopped). SARS-CoV-2 infection was defined as hospital-acquired if identified ≥8 days after admission[11]. A policy of surgical mask wearing for all staff and visitors in both clinical and non-clinical areas of the hospital was in place from before the beginning of the study period until 1st June 2022 (week 25). At this point, the mask mandate was withdrawn for staff in all non-clinical areas and most wards ('intervention group'). Masking was, however, retained in high-risk areas, namely renal, haematology and oncology wards, the medical admissions unit and the intensive care units ('control group'). Data for both groups were divided into two time segments: the pre-intervention period (4th December 2021 to 1st June 2022) and post-intervention period (2nd June 2022 to 10th September 2022).

Interrupted Time Series Analysis

Interrupted time series analysis is a quasi-experimental approach frequently used to evaluate longitudinal effects of health interventions[12]. This approach is a pragmatic solution to the common situation where performing a randomised trial is not feasible but routinely collected clinical data either side of a healthcare intervention creates a natural experiment. We used a controlled interrupted time series design which allowed us to assess for pre-intervention trends and account for potential confounders. The benefit of the control group, in particular, is to exclude 'history bias' – an unrecognised event or change that co-occurs with the intervention and also impacts the outcome (hospital-acquired SARS-CoV-2 infection rate).

The main driver of the number of hospital-acquired SARS-CoV-2 infections is the local community infection rate since this impacts all potential sources of transmission – staff, visitors, and other patients. To account for this, longitudinal hospital-acquired SARS-CoV-2 infection counts were adjusted by the local community SARS-CoV-2 infection rate as determined by the number of positive results captured on routine screening of all admitted patients, or any positive result within 7 days of admission. The outcome variable for the analysis was therefore the ratio of the hospital-acquired to community-acquired SARS-CoV-2 infections on a week-by-week basis throughout the study period.

Statistical Analysis

Simple hospital-acquired to community-acquired SARS-CoV-2 infection proportions before and after the intervention were not normally distributed and so were compared by Wilcoxon rank sum tests. A further analysis was done using a segmented quasi-poisson regression model, accounting for over-dispersed hospital-acquired SARS-CoV-2 infection count data, with the community-acquired SARS-CoV-2 infection count as an offset variable. This was fitted to both the intervention and control groups in the following form:

$$log(Y_t) = log(offset(A_s)) + \beta_0 + \beta_1 T + \beta_2 X_t + \beta_3 (T - T_0) X_t$$

where Y_t is the count of hospital-acquired SARS-CoV-2 cases, A_s is the community-acquired SARS-CoV-2 count. β_0 is the intercept, β_1 is the pre-intervention trend, β_2 is the immediate impact following intervention, and β_3 is the post-intervention trend. T is the time elapsed since the beginning of the study period. T_0 is the time of the intervention. Xt is a dummy variable representing the intervention (coded: 0 = mask period; 1 = post-mask period).

The primary outcome was an immediate change in the weekly hospital-acquired SARS-CoV-2 infections adjusted by the background rate of community infection (i.e. ratio of hospital-acquired infections to community-acquired infections) after removal of the mask mandate. The secondary outcome was a change in trend of the weekly ratio after the intervention. For both outcomes comparison was made with the control group to exclude the impact of confounding events or trends. Sensitivity analyses were performed varying the cut-off for the definition of hospital onset SARS-CoV-2 infections to ≥3 days and ≥14 days after admission.

Residual autocorrelation was tested with the Ljung–Box test[13]. Model assumptions were also assessed with autocorrelation function and partial autocorrelation function plots. Seasonal fluctuations could not be assessed as the time series only covers a 10-month period but were not expected to influence the data. Data were analysed using R version 4.2.1.[14]

Results

There were 1979 episodes of community-acquired SARS-CoV-2 infection identified on unselected admission screening during the study period, 1362 pre-intervention and 617 post-intervention (see Figure 1). In the same period, 519 episodes of hospital-acquired SARS-CoV-2 infection were identified in the intervention group. 342 were pre-intervention and 177 were post-intervention. On the wards where the mask policy was continued (the control group), there were 45 cases: 28 pre-intervention and 17 post-intervention.

Before the intervention the weekly hospital-acquired SARS-CoV-2 infections as a proportion of the community-acquired infections were a median of 0.24 (IQR: 0.14 to 0.32) and 0.016 (IQR: 0.00 to 0.034) for intervention and control groups respectively. After the intervention these proportions were a median of 0.24 (IQR: 0.19 to 0.32) and 0.025 (IQR: 0.013 to 0.038) for the intervention and control groups respectively. Pre- and post- intervention proportions for intervention and control groups were not significantly different: p=0.47; p=0.38 respectively.

Results of the controlled time series analysis are shown in Figure 2 and Table 2. Both visual inspection and regression analysis of the pre-intervention time series showed no consistent trend in the hospital-acquired SARS-CoV-2 infection rate during this period. The absence of a significant trend in the early period was also mirrored in the control group. This indicates that there were no significant time-varying factors influencing the rate of transmission in hospital over the study period.

Neither primary nor secondary outcomes reached statistical significance. After removal of the mask mandate there was no immediate change identified in the rate of hospital-acquired SARS-CoV-2 infection with an incidence rate ratio (IRR) of 1.105 (95% CI: 0.523 to 2.334; p=0.79) and similarly no post-intervention trend was observed with an IRR of 1.013 (95% CI: 0.932 to 1.100; p=0.76). In the control group, in which the mask policy was continued, there was also no evidence of either an immediate change or sustained trend.

The sensitivity analyses, which altered the hospital-acquired definition to onset ≥3 days and ≥ 14 days after admission, also found no statistically significant change for either primary or secondary outcomes.

Discussion

Despite the importance of the topic, and multiple studies, there is uncertainty over the degree of benefit conferred by masking in different settings [15]. In the absence of large-scale randomised controlled trials of masking in healthcare settings, a quasi-experimental approach such as this time-series analysis may provide useful evidence[16]. The end of the mask mandate in our hospital was followed almost immediately by a community surge in Omicron cases which naturally led to a rise in hospital-acquired cases, but our results showed that the proportion of hospital-acquired infections remained unchanged. This suggests that, among our local hospital population, if there is a benefit from a staff mask mandate policy in terms of reduced hospital spread from staff to patients, it is small and not easily detectable against the larger number of hospital-acquired infections that presumably are acquired from other sources. A concurrent mathematical modelling study by UK-HSA epidemiologists has calculated that masking in a healthcare setting is likely to be most useful early in a pandemic, or when a new immune-escaping variant emerges, but once sufficient population level-immunity has built up, there is little difference in infection rates whether masks are worn or not: this is broadly consistent with our observations from real-world data[17].

We believe that this work helps provide an empiric evidence base, previously lacking, to help inform a rational and proportionate mask policy in health services, in the current context of COVID-19 in the post-pandemic and post-vaccination era. Masking is a highly visible control measure, and its presence or absence is under more public scrutiny than other less obvious control measures such as screening, physical distancing or improving ventilation. This may explain why it was frequently retained after other control measures had been relaxed. Even after the UK NHS removed the national mask mandate in mid-2022, many hospitals retained masking well into 2023, as did many US states[18] , and mask mandates were reintroduced in multiple US healthcare facilities and institutions in August of 2023 in response to an increase in COVID-19 cases[19]. Whilst mask wearing has been shown to be associated with reduced incidence in certain settings, such as the confined quarters of a military ship early on in the pandemic[20] this does not equate to the same effect in all settings[15] especially when the severity of disease and rate of vaccination within the population has changed. As such, decisions regarding mask wearing may require a more nuanced approach than previously employed.

Although universal masking in healthcare is generally viewed as easy and cheap to implement, it does have some problems. Masks are a barrier to communication, both verbal and non-verbal [21,22], and some staff find them burdensome or a skin irritant[23,24].. Although individual masks are cheap, the vast quantity used in the pandemic has had a significant financial and environmental cost, in terms of initial manufacture, transport, and later waste disposal [25]. 1.4 billion masks were used in the UK Health and Social Care services between February 2020 and March 2021[26]. Our hospital alone, with 10,000 staff, was using 3.6 million masks yearly at the height of the pandemic.

One limitation of this study is that we were not able to use staff infection rates as a denominator for our hospital-acquired infections; we did not have access to comprehensive and validated staff infection data. However, it has previously been shown that healthcare staff COVID-19 rates correlate closely with community rates of infection[27]. In addition, the NHS mask mandate referred specifically to type IIR surgical masks, and our findings may not be applicable to other mask types. We did not formally evaluate adherence to correct mask wearing, however our own observations at the time suggested very high compliance with the mandate until the date it was removed.

Conclusion

This real-world study of 2543 cases of community-acquired and hospital-acquired SARS-CoV-2 infection over a 40-week period found that removal of a healthcare mask mandate at a late stage in the pandemic, with a high level of population vaccination and immunity, did not have a significant measurable effect on the proportion of SARS-CoV-2 infections acquired in hospital. It is important to be clear about this conclusion – we have not demonstrated that masks are ineffective, but rather that removing the staff mask mandate at this point did not lead to a significant increase in risk of infection. This provides some objective evidence to support for the removal of healthcare mask mandates in many countries through 2022 and 2023, and may help inform pragmatic decision-making in future surges and pandemics of COVID-19 or other viral respiratory infections, where the benefit of mask policies may vary over time, as the disease evolves and population immunity grows.

Acknowledgements: Many thanks to Louie Rosas, Infection Prevention and Control Information Officer, for help with collating the data on infection numbers.

Declarations of interest:

No conflicts of interest to declare.

Funding:

The authors did not receive any funding for this study.

Ethics:

Ethical approval was not required for this study.

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Figure 1.

Weekly numbers of hospital-acquired (red points) and community-acquired (blue points) SARS-CoV-2 infection. Dotted line represents the date when the mask mandate was removed.

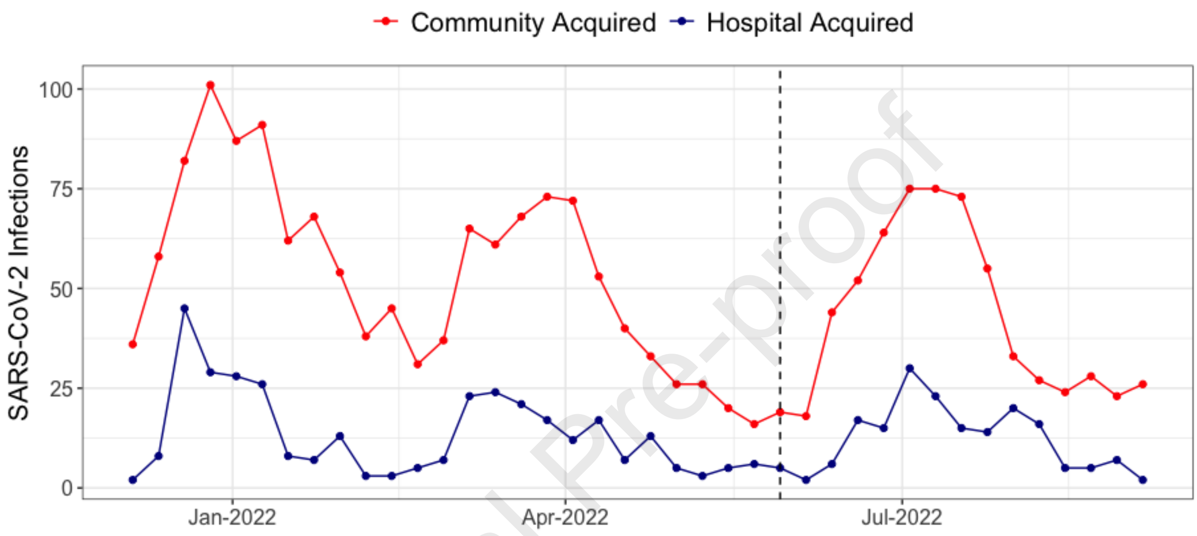

Figure 2

Hospital-acquired SARS-CoV-2 infection as a proportion of community-acquired cases. Dotted line represents the beginning of the week following withdrawal of the mask mandate. The pre-intervention and post-intervention segment trend lines are shown in red. The blue trend lines show the control group.

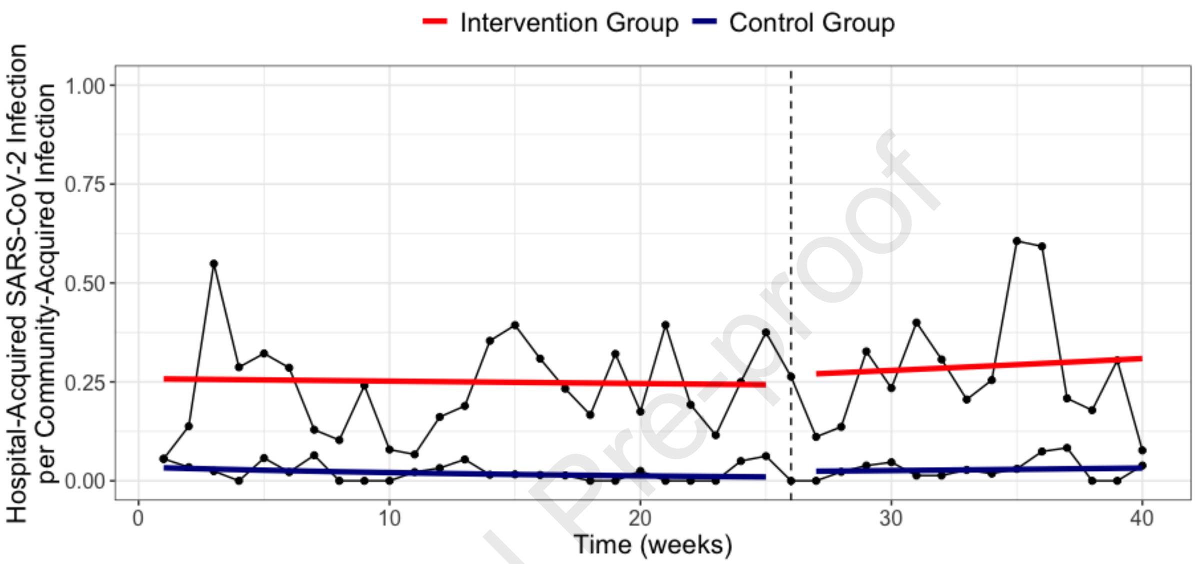

Table 1. shows monthly community-acquired episodes, and hospital acquired episodes separated into those in the intervention group (patients located on wards where the mask mandate was removed) and those in the control group (patients located on wards where the mask mandate was retained).

	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22
Community Acquired	277	362	151	267	224	81	178	311	102	26
Hospital Acquired (Control Group)	6	11	4	4	1	2	6	6	4	1
Hospital Acquired (Intervention Group)	84	82	18	85	54	19	40	102	33	2

Table 2. Results of time series analysis comparing proportion of hospital-acquired SARS-CoV-2 infection to background community-acquired rate. The coefficients of the Poisson model were exponentiated to give incidence rate ratios (IRR).

	Intervention Group			Control Group		
	IRR	CI	p-value	IRR	CI	p-value
Intercept	0.258	0.178 to 0.374	<0.001	0.035	0.018 to 0.067	<0.001
Pre-Intervention Trend	0.998	0.97 to 1.026	0.866	0.951	0.895 to 1.009	0.098
Immediate Impact	1.105	0.523 to 2.334	0.793	2.561	0.555 to 11.813	0.228
Post-Intervention Trend	1.013	0.932 to 1.100	0.764	1.075	0.923 to 1.252	0.350